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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 08/850,353 | 05/02/97 | KIM | Y PC9563JTJ |
| | | | EXAMINER |

HM32/0323

GREGG C BENSON
PFIZER INC
PATENT DEPARTMENT
EASTERN POINT ROAD
GROTON CT 06340

| | |
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| WHITE, E | PAPER NUMBER |
| ART UNIT | 3 |

1623

DATE MAILED: 03/23/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-15 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 1-3 is/are allowed.
- ☒ Claim(s) 4-15 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

1. The disclosure is objected to because of the following informalities: Page 2, line 3, the closing parenthesis should be canceled; page 8, line 21, this first occurrence of the term "SBECD" should be changed to ---sufobutyl ether β -cyclodextrin (SBECD)---.

Appropriate correction is required.

2. Claims 4-6 are objected to because of the following informalities: The phrase "composition of matter" should be changed to ---composition---. Appropriate correction is required.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 4-6 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryant et al. (US Patent No. 5,624,940).

Applicant broadly claims a composition comprising a salt of a compound and a cyclodextrin obtained by a particular method (see claims 1, 2 and 3).

Bryant et al disclose an aqueous solution inclusion complex or a salt thereof comprising a benzothiophene of formula I (see column 1, lines 11-33). The salt of the Benzothiophene of formula I in the Bryant et al patent is within the scope of a "salt of a compound" in the instant claims. However, Bryant et al does not disclose obtaining the complex as set forth in claims 1-3 of the instant application. While Applicant claims are directed to a product limited by the process employed in its production there is no reason found for concluding that the product claimed could be distinguished from the product of the Bryant et al. patent merely because the claimed product was produced under the specific conditions recited, which conditions fall within the purview of the disclosure of the Bryant et al. patent. Note In re Kern, 48 CCPA 1023; 1961 C.D. 425; In re

Smith, 34 CCPA 1202; 1947 C.D. 536. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was employed having the Bryant et al patent before him to prepare the instant claimed composition in view of their closely related cyclodextrin structure and similar ingredients of the composition and the resulting expectation of the cyclodextrin compositions having similar solubility properties.

5. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szejtli et al. (US Patent No. 4,228,160).

Applicant broadly claims a composition comprising a salt of a compound and a cyclodextrin wherein the composition is a physical mixture of said salt and said cyclodextrin which were obtained by a particular method (see claims 1, 2 and 3).

Szejtli et al disclose an inclusion complex of cyclodextrin and indomethacin and further show that a physical mixture of an ammonium salt of indomethacin and cyclodextrin is well known in the art (See column 2, lines 26-33). The ammonium salt of indomethacin which is disclosed in the Szejtli et al patent is within the scope of the instant claimed "salt of a compound". However, the Szejtli et al patent differ from the claimed composition since the Szejtli et al patent does not disclose obtaining the complex as set forth in claims 1-3 of the instant application. Again, while Applicant claims are directed to a product limited by the process employed in its production there is no reason found for concluding that the product claimed could be distinguished from the product of the Szejtli et al. patent merely because the claimed product was produced under the specific conditions recited, which conditions fall within the purview of the disclosure of the Szejtli et al. patent. Note In re Kern, 48 CCPA 1023; 1961 C.D. 425; In re Smith, 34 CCPA 1202; 1947 C.D. 536. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was employed having the Szejtli et al patent before him to prepare the instant claimed composition in view of their closely related cyclodextrin structure and similar ingredients in the composition and the resulting expectation of the cyclodextrin compositions having similar hydrophilic properties.

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6. Claims 1-3 are allowed.

7. Summary: Claims 1-3 are allowed; claims 4-15 are rejected.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kight, can be reached on (703) 308-0204. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

White
March 19, 1998



JOHN KIGHT
SUPERVISORY PATENT EXAMINER
GROUP 1200